

REMARKS

Claims 1 through 20 are pending in the Present Application. Claims 1 through 6 and 10 through 14 are canceled herein, and claims 21 through 24 are added as new claims. Claims 7 through 9 and 15 through 20 are rejected in the Office Action under 35 U.S.C. § 102(b) (“Section 102(b)”) as being anticipated by U.S. patent 5,717,113 to McLaughlin et al. or, alternatively, as being anticipated by the article entitled “Evaluation of the Pawpaw Tree, *Asimina Triloba* (Annonaceae), as a Commercial Source of the Pesticidal Annonaceous Acetogenins” by Ratanayake et al. (“Ratanayake et al.”). Claims 7 through 9 and 15 through 20 are also rejected in the Office Action under 35 U.S.C. § 103(a) (“Section 103(a)”) as being unpatentable over McLaughlin et al. in view of Ratanayake et al. Applicants respectfully traverse these rejections and request reconsideration of the present application in light of the remarks that follow.

Applicants further note that claims 21 through 24 are added to the present application through this Amendment. Claims 21 through 24 depend from claim 20 and, therefore, incorporate all of the features of the method recited in claim 20.

I. Rejection Under Section 102(b)

Claims 7 through 9 and 15 through 20 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. patent 5,717,113 to McLaughlin et al. (“McLaughlin et al.”) or, alternatively, as being anticipated by the article entitled “Evaluation of the Pawpaw Tree, *Asimina Triloba* (Annonaceae), as a Commercial Source of the Pesticidal Annonaceous Acetogenins” by Ratanayake et al. (“Ratanayake et al.”). Applicants respectfully traverse this rejection because neither of these cited references teaches each and every element of the rejected claims. Moreover, because claim 8 and claims 10 through 14 are canceled herein, Applicants respectfully note that the rejection of such claims under Section 102(b) is no longer relevant.

A claim is anticipated under Section 102(b) only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in the cited reference in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

In this instance, claims 7 and 15 through 19 recite methods for preparing a crude extract containing one or more acetogenin compound. The methods recited in these claims require standardizing the crude extract for zero percent moisture and an LC₅₀ of 0.5 ppm in a BST. However, such a step is not expressly or inherently taught by McLaughlin et al. or by Ratanayake et al. Therefore, Applicants respectfully submit that neither reference anticipates claim 7 or claims 15 through 19, and Applicants request that the rejection of these claims under Section 102(b) be withdrawn.

With reference to the Ratanayake et al. reference, the document provides an evaluation of the suitability of the pawpaw tree as a commercial source of *pesticidal* Annonaceous acetogenins. Though the reference indicates that Annonaceous acetogenins have been reported to possess antitumor activity, Ratanayake et al. is entirely focused on the viability of using extracts from one representative of the Annonaceae family (the pawpaw tree) for pesticidal purposes, not human consumption. Moreover, the teachings found in the Ratanayake et al. reference do not expressly or inherently teach a method that includes standardizing a crude extract to zero percent moisture and an LC₅₀ of 0.5 ppm in a BST. The Ratanayake et al. reference simply can not support the rejection of claims 7 and 15 through 19 under Section 102(b), and Applicants respectfully request that the rejection of these claims in light of Ratanayake et al. be withdrawn.

The McLaughlin et al. document recognizes that Annonaceous acetogenins are often bioactive, even characterizing their activity as “potent” and potentially useful as cytotoxic agents that may be used as antitumor or antileukemic agents. However, the teachings of McLaughlin et al. focus on isolating specific acetogenins and acetogenin derivatives as possibly therapeutic drugs. The teachings of McLaughlin et al. are not concerned with crude extracts or methods of producing such extracts. Therefore, the McLaughlin et al. reference includes no express or inherent teaching regarding a method for preparing a crude extract containing one or more acetogenin compound that includes the step of standardizing the crude extract to zero percent moisture and an LC₅₀ of 0.5 ppm in a BST. Consequently, McLaughlin et al. can not support a rejection of claims 7 and 15 through 19 under Section 102(b), and Applicants respectfully request that the rejection of these claims as anticipated by McLaughlin be withdrawn.

Similarly, claims 9 and 20 also recite methods for preparing a crude extract containing one or more acetogenin compound. The methods recited in these claims differ from those recited in claims 7 and 15 through 19. Specifically, the methods recited in claims 9 and 20 require standardizing the crude extract for a range of 10-40% moisture, and an LC₅₀ value in a range of 0.2-0.8 ppm in a BST. New claims 21 through 24, which are added by this Amendment, depend from claim 20 and, as a result, also include the step of standardizing the crude extract for a range of 10-40% moisture, and an LC₅₀ value in a range of 0.2-0.8 ppm in a BST. As was the case for claims 7 and 15 through 19, the teachings of McLaughlin et al. and Ratanayake et al. are simply not directed to methods as recited in claims 9 and 20, and the teachings found in these references fail to expressly or inherently teach methods for preparing a crude extract containing one or more acetogenin compound that includes the step of standardizing the crude extract for a range of 10-40% moisture, and an LC₅₀ value in a range of 0.2-0.8 ppm in a BST. Therefore, Applicants respectfully submit that neither McLaughlin et al. nor Ratanayake et al. anticipates claim 9 or claim 20, and Applicants respectfully request that the rejection of claims 9 and 20 under Section 102(b) be withdrawn. Because claims 21 through 24 depend from claim 20 and incorporate all the features of claim 20, Applicants further submit that the teachings of McLaughlin et al. nor Ratanayake et al. do not anticipate any of claims 21 through 24.

II. Rejection Under Section 103(a)

Claims 7 through 9 and 15 through 20 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Ratnayake et al in light of McLaughlin et al. Applicants respectfully traverse this rejection because neither of these cited references teaches or suggests methods having all the features recited in the rejected claims. Moreover, the combined teachings of the cited references actually teach away from the pending claims and could not be combined to achieve the methods recited in the pending claims. Therefore, Applicants respectfully request withdrawal of the rejection of claims 7 through 9 and 15 through 20. Moreover, because claim 8 and claims 10 through 14 are canceled herein, Applicants respectfully note that the rejection of such claims under Section 103(a) is no longer relevant.

It is well settled that the PTO has the burden to establish a *prima facie* case of obviousness. See MPEP § 2142. “If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness.” *Id.* According to MPEP § 2143.03, to establish a *prima facie* case of obviousness, “all of the claim limitations must be taught or suggested by the prior art.” (citing *In re Royka*, 490 F.2d 981, 180 USPQ 580 (C.C.P.A. 1974)). “If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious.” MPEP §2143.03, citing *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). It is also well established that if the references themselves teach away from their combination, then such teaching away by itself defeats any assertion of *prima facie* obviousness. See MPEP §2145; Winner Int’l Royalty Corp. v. Wang, 53 USPQ2d 1580, 1587 (Fed. Cir. 2000); *In re Grasselli*, 218 USPQ 769, 779 (Fed. Cir. 1983).

As was detailed in the preceding discussion, the claims pending in the present application are directed to methods of preparing a crude extract containing one or more acetogenin compound. Claims 7 and 15 through 19 recite methods that include standardizing the crude extract for zero percent moisture and an LC₅₀ of 0.5 ppm in a BST, while claims 9 and 20 through 24 recited methods that include standardizing the crude extract for a range of 10-40% moisture, and an LC₅₀ value in a range of 0.2-0.8 ppm in a BST. The combined teachings of McLaughlin et al. and Ratnayake et al. fail to teach or suggest methods that include such steps. Again, the teachings of Ratnayake et al. are directed to evaluating the pawpaw tree as a commercial source of acetogenin compounds for use as pesticides. This references does not teach or suggest methods for preparing crude extracts that are suitable for human consumption, as is recited in claims 7 and 15 through 19. Moreover, the teachings of Ratnayake et al. fail to teach or suggest methods for preparing crude extracts that include standardizing the crude extracts to exhibit the particular moisture contents or LC₅₀ performance recited in the pending claims. Therefore, Ratnayake et al. does not teach or suggest each of the limitations recited in the pending claims.

Moreover, the teachings of McLaughlin et al. do not combine with the teachings of Ratnayake et al. to teach or suggest each of the limitations recited in the pending claims. In particular, the teachings of McLaughlin et al. focus on the isolation of particular acetogenin compounds, not the production of crude extracts. The teachings of McLaughlin et al. are completely void of any teaching or suggestion of a method for preparing a crude extract containing one or more acetogenin compounds that includes standardizing the crude extract to exhibit the particular moisture contents or LC₅₀ performance recited in the pending claims. Therefore, the combined teachings of Ratnayake et al. and McLaughlin et al. fail to establish the *prima facie* obviousness of claims pending in this application, and the rejection of claims 7, 9, 15 through 19 and 20 should be withdrawn. Because, claims 21 through 24 depend from claim 20 and incorporate all of the features of the method recited in claim 20, the combined teachings of Ratnayake et al. and McLaughlin et al. also fail to establish the *prima facie* obviousness of claims 21 through 24.

Applicants further emphasize that one of ordinary skill in the art could not combine the teachings of Ratnayake et al. and McLaughlin et al. to arrive at the methods recited in the claims now pending in the present application. In particular, the McLaughlin et al. reference teaches away from the use of crude extracts of any sort and focus entirely on the isolation of particular acetogenin compounds. Given the teachings of McLaughlin et al., particularly the continual emphasis on the isolation of individual acetogenin compounds, one of ordinary skill in the art would read McLaughlin et al. as promoting only the utility and value of isolated compounds. Therefore, one of ordinary skill could only read McLaughlin et al. as teaching away from the pending claims, which are directed to the preparation of crude extracts containing one or more acetogenin compounds. The combined teachings of Ratnayake et al. and McLaughlin et al. not only fail to teach or suggest all of the limitations recited in the pending claims, but the combined teachings of these references, when considered as a whole, could only fairly be read to teach away from the subject matter recited in claims 7, 9, and 15-24 of the present application, and applicants again request withdrawal of the rejection of claims 7, 9 and 15 through 20 under Section 103(a).

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CONCLUSION

Applicants respectfully assert that claims 7, 9, and 15 through 24 are patentably distinct from the cited references, and request that a timely Notice of Allowance be issued in this case. If there are any remaining issues preventing allowance of the pending claims that may be clarified by telephone, the Examiner is requested to call the undersigned.

Respectfully submitted,



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